Claim 23 has also been amended to clarify that the instructions for use indicate that the identification of an *Ehrlichia* infection is done using the recited method. This amendment is not a narrowing amendment and merely clarifies the claimed subject matter.

No new matter is added by these amendments. Applicants respectfully request entry of these amendments and new claims.

An Office Action was issued in this case on September 4, 2002. Applicants have provided comments on the Office Action below.

Rejection of Claims 21-24 Under 35 U.S.C. §112, first paragraph

Claims 21-24 stand rejected under 35 U.S.C. §112, first paragraph as allegedly lacking written description. Applicants respectfully traverse the rejection.

The Office Action asserts that variants of SEQ ID NOs:1-7 are not adequately described in the specification. The standard for written description is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, the Applicant was in possession of the invention as now claimed. *See Vas-Cath, Inc. v. Mahurkar*, 19 U.S.P.Q.2d 1111, 1117 (Fed. Cir. 1991). An Applicant shows possession of the claimed invention with all of its limitations using such descriptive words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. See *id.* Furthermore:

> conception [and therefore possession] of a chemical compound requires that the inventor be able to define it so as to distinguish it from other materials, and to describe how to obtain it. Conception does not occur unless one has a mental picture of the structure of the chemical, or is able to define it by its method of preparation, its physical or chemical properties, or whatever characteristics sufficiently distinguish it. It is not

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> sufficient to define it solely by its principal biological property, e.g., encoding human erythropoietin, because an alleged conception having no more specificity than that is simply a wish to know the identity of any material with that biological property. *See Amgen, Inc. v. Chugai Pharmaceutical Co.*, 18 U.S.P.Q.2d 1016, 1021 (Fed. Cir. 1991).

Claims 21 and 23 have been amended to recite that the variants of SEQ ID NOs:1-7 are phenotypically silent amino acid substitution variants. Additionally, new claims 35-38 have been added. These claims recite that the variants of SEQ ID NOs:1-7 are conservative amino acid substitution variants. Given the specification, one of skill in the art would recognize that the Applicants were in possession of isolated polypeptides of SEQ ID NOs:1-7, phenotypically silent amino acid substitution variants of SEQ ID NOs;1-7, and conservative amino acid substitution variants of SEQ ID NOs:1-7.

The specification teaches that variants of the invention can be phenotypically silent amino acid substitutions and/or conservative amino acid substitutions and provides detailed guidance on how to construct such variants. See, page 7, line 10 through page 8, line 20. *See also*, Bowie, et al., *Science*, 247:1306(1990) (copy attached) (teaching methods of construction of variants and the tolerance of protein sequences of substitutions).

The specification teaches that: "[p]olypeptides that do not comprise 100% identity to a polypeptide sequence shown in SEQ ID NOs:1-7 are considered 'variants'" and that "the invention provides polypeptides having at least 85% identity, more preferably at least 90% identity, and still more preferably at least 96%, 97%, 98%, or 99% identity to a polypeptide sequence shown in SEQ ID NOs:1-7." See page 5, lines 5-14.

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The specification goes on to define the meaning of "identity" and explains that sequences are aligned for identity calculations using a mathematical algorithm. See page 6, line 3 through page 7, line 5. The specification furthermore provides guidance concerning how to make phenotypically silent amino acid substitutions. See page 7, line 10 through page 8, line 20.

The specification also specifies that :

> Polypeptides of the invention specifically bind to an anti-*Ehrlichia* antibody. In this context "specifically binds" means that the polypeptide recognizes and binds to an anti-*Ehrlichia* antibody, but does not substantially recognize and bind other molecules in a test sample. See page 9, lines 8-11.

The specification also teaches how to screen a variant polypeptide to determine whether it binds to an anti-*Ehrlichia* antibody. See, e.g., page 18, line 19 through page 19, line 13.

Therefore, the specification teaches that a phenotypically silent amino acid substitution variant or conservative amino acid substitution variant polypeptide of the invention has at least 85% identity, more preferably at least 90% identity, and still more preferably at least 96%, 97%, 98%, or 99% identity to a polypeptide sequence shown in SEQ ID NOs:1-7, and that it specifically binds to an anti-*Ehrlichia* antibody. One of skill in the art would recognize that variations can be made in a polypeptide shown in SEQ ID NO:1-7 without affecting antigenecity. See specification page 8, lines 9-20 (teaching that proteins are surprisingly tolerant of amino acid substitutions and providing guidance to the types of amino acid substitutions that are well tolerated). Furthermore, one of skill in the art would recognize that the Applicants were in possession of variant polypeptides

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having a certain percentage sequence identity to SEQ ID NOs:1-7, comprising either phenotypically silent amino acid substitutions or conservative amino acid substitutions, and that also specifically bind an anti-*Ehrlichia* antibody.

Applicants demonstrated possession of phenotypically silent amino acid substitution variants and conservative amino acid substitution variants of SEQ ID NOs:1-7. The physical and chemical properties of such variants have been described such that one of skill in the art would recognize that the applicants were in possession of the claimed variants and were able to distinguish the claimed materials from other materials when the application was filed. For example, the specification teaches that the variants are phenotypically silent amino acid substitutions or conservative amino acid substitutions, that the variants have at least 85% identity to SEQ ID NO:2, that the variants specifically bind to an anti-*Ehrlichia* antibody, and the specification teaches how to make and test the claimed variants. Therefore, the claimed variants have adequate written description in the specification.

Applicants respectfully request withdrawal of the rejection.

Rejection of Claims 21-24 Under 35 U.S.C. §112, first paragraph

Claims 21-24 stand rejected under 35 U.S.C. §112, first paragraph as allegedly lacking enablement. Applicants respectfully traverse the rejection.

The Office Action asserts that the specification does not provide enablement for a device that contains variants of SEQ ID NOs:1-7. The claims have been amended to recite that the variants are either phenotypically silent amino acid substitution variants of SEQ ID NO:2 or conservative amino acid substitution variants of SEQ ID NO:2. Under

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35 U. S. C. § 112, all that is required is that the specification describe the invention in such terms as to enable a person skilled in the art to make and use the invention. Thus, the specification must teach one skilled in the art how to make and use a phenotypically silent amino acid substitution variants or conservative amino acid substitution variants of a polypeptide shown in SEQ ID NOs:1-7. The test of enablement is whether one reasonably skilled in the art (1) could make and use the invention (2) from the disclosures in the patent coupled with information known in the art (3) without undue experimentation. *In re Wands*, 858 F.2d 731 (Fed. Cir. 1988); *United States v. Telectronics, Inc.*, 857 F.2d 778 (Fed. Cir. 1988); M.P.E.P. § 2164.01. "The determination of what constitutes undue experimentation is a given case requires the application of a standard of reasonableness, having due regard of the nature of the invention and the state of the art." *In re Wa*nds, 8 U.S.P.Q.2d 1400, 1404 (Fed. Cir. 1988) (citing *Ansul Co. v. Uniroyal, Inc.*, 169 U.S.P.Q. 759, 762-63 (2d Cir. 1971).

The specification teaches that a variant polypeptide of the invention has at least 85% identity, more preferably at least 90% identity, and still more preferably at least 96%, 97%, 98%, or 99% identity to a polypeptide sequence shown in SEQ ID NOs:1-7 and it specifically binds to an anti-*Ehrlichia* antibody. One of skill in the art could easily design and make a polypeptide that falls within the given percentage sequence identity and screen it for specific binding to an anti-*Ehrlichia* antibody. For example, in the case of SEQ ID NOs:1-7, which are about 18-20 amino acid long polypeptide, a variant polypeptide having 85% identity would have only about 3 substituted amino acids. According to the claims these substituted amino acids are phenotypically silent amino

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acid substitutions or conservative amino acid substitutions. One of skill in the art, given the specification, could easily design and make such a phenotypically silent amino acid substitution variant polypeptide or conservative amino acid substitution variant polypeptide given SEQ ID NOs:1-7. *See e.g.,* page 7, line 10 through page 8, line 20.

One of skill in the art can clearly make a polypeptide once the sequence was designed. Additionally, the specification teaches that a polypeptide can be made by, for example, conventional peptide synthesis or by recombinant techniques. See page 10, lines 6-13. One of skill in the art could then screen a variant polypeptide for binding to an anti-*Ehrlichia* antibody by the methods described in Example 1.

The law is well settled that the test of enablement "is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed." *In re Wa*nds, 8 U.S.P.Q.2d 1400, 1404 (Fed. Cir. 1988) (citing *Ansul Co. v. Uniroyal, Inc.*, 169 U.S.P.Q. 759, 762-63 (2d Cir. 1971)). One of skill in the art understands the meaning of sequence identity and most certainly could design and make a polypeptide sequence that has 85% or more sequence identity to SEQ ID NO:1-7 using only routine experimentation. Once one of skill in the art had designed and made a phenotypically silent amino acid substitution variant polypeptide or conservative amino acid variant polypeptide of the invention, they could use only routine screening to identify whether the polypeptide specifically binds to an anti-*Ehrlichia* antibody. Therefore, even though it could conceivably take a considerable amount of experimentation to design and make a phenotypically silent

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amino acid substitution variant polypeptide or conservative amino acid variant polypeptide of the invention, such design and manufacture requires only routine experimentation that is well-known and understood to one of skill in the art. Additionally, the specification provides direction to guide one of skill in the art to the experimentation that is necessary to design, make and screen a phenotypically silent amino acid substitution variant polypeptide or conservative amino acid variant polypeptide of the invention.

Finally, the specification teaches that a phenotypically silent amino acid substitution variant polypeptide or conservative amino acid variant polypeptide can be used to detect the presence of anti-*Ehrlichia* antibodies. See page 11, line 22 through page 17, line 9. Therefore, one of skill in the art, given the specification could make and use the phenotypically silent amino acid substitution variant polypeptide or conservative amino acid variant polypeptide of the invention without undue experimentation.

Applicants respectfully request withdrawal of the rejection.

Rejection of Claims 21-24 Under 35 U.S.C. §102(a)

Claims 21-24 stand rejected under 35 U.S.C. §102(a) as allegedly anticipated by Waner *et al.* Applicants respectfully traverse the rejection.

Anticipation under 35 U.S.C. §102 requires the presence in a single prior art disclosure of each and every element of a claimed invention. *Lewmar Marine Inc. v. Barient Inc.*, 3 U.S.P.Q.2d 1766, 1767 (Fed. Cir. 1987).

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The claims recite devices containing an isolated polypeptide shown in SEQ ID NOs:1-7, phenotypically silent amino acid substitution variants of SEQ ID NOs:1-7, and conservative amino acid substitution variants of SEQ ID NOs:1-7.

The Office Action asserts that Waner teaches a commercial ELISA for *E. canis* and that the polypeptides recited in the instant invention would be inherent in the teachings of Waner.

Initially it should be noted that SEQ ID NOs:3-7 are derived from *E. chaffeensis* (see Table 1 of specification) and that Waner does not teach any *E. chaffeensis* sequences. As such Waner cannot anticipate devices containing SEQ ID NOs:3-7. Additionally, Waner does not teach or suggest the use of distinct polypeptides as shown in SEQ ID NOs:1-7. That is, Waner does not teach or suggest about 18-20 amino acid polypeptides of SEQ ID NOs:1-7 or the specified variants of SEQ ID NOs:1-7. Instead, Waner teaches an IFA for *Ehrlichia canis* that uses DH82 cells that are heavily infected with *E. canis* as an antigen. See page 240, second column, last paragraph. Waner also teaches an ELISA for *E. canis* that uses an *E. canis* antigen derived from mouse J774.A1-infected cells. See page 241, first column, first full paragraph. Waner, therefore, teaches entire cells or whole proteins as assay antigens. As such, Waner cannot teach, suggest, or inherently disclose the specific, individual polypeptides shown in SEQ ID NOs:1-7 or the specified variants of SEQ ID NO:1-7. Furthermore, Waner does not identify the polypeptide fragments to be of any particular diagnostic use. There is no teaching in Waner, directly or inherently, that would direct one of skill in the art to the particular defined sequences of SEQ ID NOs:1-7 or the specified variants for any reason. Warner

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does not teach or suggest that polypeptides of SEQ ID NOs:1-7 would be useful as individual polypeptides apart from entire *E. canis* infected cells or entire proteins. Warner provides no recognition or suggestion that the distinct polypeptides shown in SEQ ID NOs:1-7 or the specified variants or any other polypeptide fragments would be of diagnostic use.

Importantly, the specification teaches that:

> Indirect immunofluorescense assays (IFA) and enzyme-linked immunosorbent assays (ELISA) are frequently used as aids in the diagnosis of these diseases. These assays measure or otherwise detect the binding of anti-*Ehrlichia* antibodies from a patient's blood, plasma, or serum to infected cells, cell lysates, or purified *Ehrlichia* proteins. However, currently known assays for detecting anti-*Ehrlichia* antibodies or fragments thereof are severely limited in usefulness because of sensitivity and specificity issues directly related to the impure nature of the *Ehrlichia* antigen used in these tests. See page 2, line 21 through page 3, line 2 (emphasis added).

The instant invention provides highly purified reagents for the detection *Ehrlichia*, that is, polypeptides of about 18-20 amino acids, whereas Waner teaches the use of reagents comprising whole infected cells or whole *E. canis* proteins derived from infected cells. The Waner reagents are impure reagents, which the instant specification teaches are of limited usefulness due to the sensitivity and specificity issues. For instance, Example 1 demonstrates that assays that use a synthetic peptide were more sensitive and specific than assays that use native *E. canis* antigens, i.e., partially purified *E. canis* antigens

Additionally, the Office Action is relying on an inherency theory to sustain this anticipation rejection. However, where an Examiner relies upon an inherency theory:

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> the Examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art. See *Ex parte Levy*, 17 U.S.P.Q. 1461,1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original); M.P.E.P. §2112.

The Office Action has provided no reasoning or evidence tending to show inherency in the instant case. Rather, the Office Action relies upon the statement the article of manufacture "appears" to be the same as the claimed invention and baldly asserts that the claimed polypeptides are "inherent in the teachings of the prior art" without providing any reasoning or evidence why the claimed about 18-20 amino acid polypeptides as shown in SEQ ID NOs:1-7 would be present in Waner. The Office Action asserts that it does not have the facilities for examining and comparing the claimed compositions and articles with the device of the prior art and asserts that the burden is on the applicant to show a novel or unobvious difference between the claimed product ant the product of the prior art. However, the initial burden of establishing a *prima facia* basis to deny patentablity to a claimed invention rests upon the examiner. See *Ex parte Levy* at 1463-1464. The Examiner has not discharged this initial burden in this case.

Furthermore, the Office Action has provided no extrinsic evidence, other than a bald assertion, to support the alleged inherency finding.

> To establish inherency, the extrinsic evidence "must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill." Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient. *See In re Robertson*, 49 U.S.P.Q.2d 1949, 1950-1951 (Fed. Cir. 1999) (citations omitted); M.P.E.P §2112.

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The Office Action has provided no extrinsic evidence that the claimed about 18-20 amino acids polypeptides are present in the cited reference.

Finally, the Office Action asserts that:

> It should be noted that the claimed device contains polypeptides that detect *Ehrlichia* infection wherein the infection is caused by *Ehrlichia canis* or *Ehrlichia chaffeensis* and that the polypeptides detect the presence of *Ehrlichia* antibodies not that the claimed polypeptides are from *Ehrlichia canis* or *Ehrlichia chaffeensis*.

The Office Action appears to be asserting that any polypeptide that detects *Ehrlichia* infection wherein the infection is caused by *E. canis* or *E. chaffeensis* would anticipate the claimed invention. However, the claims clearly recite that the claimed devices contain one or more polypeptides selected from the group consisting of the polypeptides shown in SEQ ID NOs:1-7, phenotypically silent amino acid substitution variants thereof, and conservative amino acid substitution variants thereof. Waner does not teach or suggest the use of the specified polypeptides and as such, cannot anticipate the claims.

Waner does not anticipate claims 21-24 because Waner does not teach, suggest, or inherently disclose each and every element of claims 21-24. Applicants respectfully request withdrawal of the rejection.

Rejection of Claims 21-24 Under 35 U.S.C. §102(b)

Claims 21-24 stand rejected under 35 U.S.C. §102(b) as allegedly anticipated by Cadman *et al.* Applicants respectfully request withdrawal of the rejection.

Similar to the Waner rejection above, the Office Action asserts that the devices of the invention are inherently present in the assays disclosed in Cadman.

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Initially it should be noted that SEQ ID NOs:3-7 are derived from *E. chaffeensis* (see Table 1 of specification) and that Cadman does not teach any *E. chaffeensis* sequences. As such Cadman cannot anticipate devices containing SEQ ID NOs:3-7. Additionally, Cadman does not teach or suggest the use of distinct polypeptides as shown in SEQ ID NOs:1-7 and the claimed specified variants. That is, Cadman does not teach or suggest an about 18-20 amino acid polypeptide of SEQ ID NO:1-7 or the specified variants. Cadman teaches an IFA for *Ehrlichia canis* that uses DH82 cells which are heavily infected with *E. canis* as an antigen. See Cadman, first column, fourth paragraph. Cadman also teaches a dot-blot enzyme linked immunoassay (DBELIA) for *E. canis* that uses an *E. canis* antigen purified from infected DH82 cells. See Cadman, first column, fifth paragraph. As such, Cadman teaches the use of whole *E. canis* infected cells or whole proteins purified from *E. canis* infected cells in the disclosed assays. Therefore, Cadman does not teach, suggest, or inherently disclose the specific, individual polypeptides shown in SEQ ID NOs:1-7 and does not identify the polypeptide fragments to be of any particular diagnostic use. There is no teaching in Cadman, directly or inherently, that would direct one of skill in the art to the particular, defined sequences of SEQ ID NOs:1-7 or specified variants for any reason. Cadman does not teach or suggest that polypeptides of SEQ ID NOs:1-7 or specified variants would be useful as individual polypeptides apart from entire *E. canis* infected cells or entire proteins. Cadman provides no recognition or suggestion that the distinct polypeptides shown in SEQ ID NOs:1-7, specified variants, or any other polypeptide fragments would be of diagnostic use.

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Additionally, Cadman teaches the use of impure reagents, i.e., whole *E. canis* infected cells or whole proteins derived from infected cells. The instant invention, however, provides highly purified reagents that are much more sensitive and specific. See e.g., specification page 2, line 21 through page 3, line 2. For instance, Example 1 demonstrates that assays that use a synthetic peptide were more sensitive and specific than assays that use native *E. canis* antigens, i.e., partially purified *E. canis* antigens.

Additionally, as discussed above, for Warner, the Office Action has not provided a *prima facia* basis to deny patentablity because the Office Action has not provided a basis in fact, technical reasoning, and/or extrinsic evidence to demonstrate that the claimed polypeptides are present in the Cadman devices.

Finally, the Office Action asserts that:

> It should be noted that the claimed device contains polypeptides that detect *Ehrlichia* infection wherein the infection is caused by *Ehrlichia* canis or *Ehrlichia chaffeensis* and that the polypeptides detect the presence of *Ehrlichia* antibodies not that the claimed polypeptides are from *Ehrlichia canis* or *Ehrlichia chaffeensis*.

The Office Action appears to be asserting that any polypeptide that detects *Ehrlichia* infection wherein the infection is caused by *E. canis* or *E. chaffeensis* would anticipate the claimed invention. However, the claims clearly recite that the claimed devices contain one or more polypeptides selected from the group consisting of the polypeptides shown in SEQ ID NOs:1-7, phenotypically silent amino acid substitution variants thereof, and conservative amino acid substitution variants thereof. Cadman does not teach or suggest the use of the specified polypeptides and as such, cannot anticipate the claims.

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Cadman does not teach each and every element of the claimed invention and therefore does not anticipate the claimed invention. Applicants respectfully request withdrawal of the rejection.

Rejection of Claims 21-26 Under 35 U.S.C. §102(b)

Claims 21-26 stand rejected under 35 U.S.C. §102(b) as allegedly anticipated by Zhi. Applicants respectfully traverse the rejection.

The Office Action asserts that the polypeptides and devices of the invention are inherently present in the assays reported in Zhi. Initially, Zhi teaches assays for the detection of Human Granulocytic Ehrlichiosis Agent (HGE). HGE is closely related to or identical to *E. equi* and *E. phagocytophilia.* See CDC Publication, "Human Ehrlichioisis in the United States;" Dumler *et al.*, Int. J. Syst. Evol. Microbiol. 51:2145 (2001) (abstract) (copy attached). Therefore, Zhi does not teach or suggest *E. canis* and/or *E. chaffeensis* antigens, proteins or polypeptides or devices containing *E. canis* and/or *E. chaffeensis* polypeptides, including polypeptides shown in SEQ ID NOs:1-7 or specified variants thereof. However, in the event that the HGE taught in Zhi could be considered to be *E. canis* or *E. chaffeensis*, Zhi would still not teach or suggest each and every element of claims 21-24.

Zhi teaches Western immunoblot analysis and dot immunoblot assays for HGE that uses HGE rP44, a 35kDa fusion protein, or purified HGE organisms as assay antigens. See page 1668, first column, first and second full paragraphs; page 1668, second column, first full paragraph.

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Zhi does not teach or suggest the use of distinct *E. canis* or *E. chaffeensis* polypeptides as shown in SEQ ID NOs:1-7 or the specified variants. Rather, Zhi teaches the use of HGE rP44 or purified HGE organisms in the disclosed assays. Therefore, Zhi does not teach, suggest, or inherently disclose the specific, individual polypeptides shown in SEQ ID NOs:1-7, or specified variants thereof and does not identify polypeptide fragments to be of any particular diagnostic use. There is no teaching in Zhi, directly or inherently, that would direct one of skill in the art to the particular, defined sequences of SEQ ID NOs:1-7 for any reason. Zhi does not teach or suggest that SEQ ID NOs:1-7 are sequences that would be useful as individual peptides apart from entire HGE organisms or HGE rP44. Zhi provides no recognition or suggestion that the distinct polypeptides shown in SEQ ID NOs:1-7 or the specified variants would be of diagnostic use.

Additionally, as discussed above, for Warner, the Office Action has not provided a *prima facia* basis to deny patentablity because the Office Action has not provided a basis in fact, technical reasoning and/or extrinsic evidence to demonstrate that the claimed polypeptides are present in the Zhi devices.

Finally, the Office Action asserts that:

> It should be noted that the claimed device contains polypeptides that detect *Ehrlichia* infection wherein the infection is caused by *Ehrlichia* canis or *Ehrlichia chaffeensis* and that the polypeptides detect the presence of *Ehrlichia* antibodies not that the claimed polypeptides are from *Ehrlichia canis* or *Ehrlichia chaffeensis*.

The Office Action appears to be asserting that any polypeptide that detects *Ehrlichia* infection wherein the infection is caused by *E. canis* or *E. chaffeensis* would anticipate the claimed invention. However, the claims clearly recite that the claimed devices

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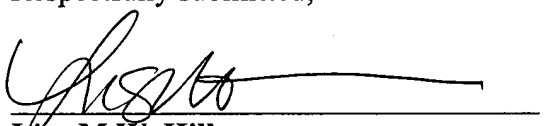
contain one or more polypeptides selected from the group consisting of the polypeptides shown in SEQ ID NOs:1-7, phenotypically silent amino acid substitution variants thereof, and conservative amino acid substitution variants thereof. Zhi does not teach or suggest the use of the specified polypeptides and as such, cannot anticipate the claims.

Zhi does not anticipate claims 21-24 because Zhi does not teach, suggest, or inherently disclose each and every element of claims 21-24. Applicants respectfully request withdrawal of the rejection.

Applicants respectfully request the withdrawal of all rejections and the speedy allowance of the claims.

Respectfully submitted,

Date: Nov. 22, 2002 By: 

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MARKED-UP VERSION OF CLAIMS TO SHOW CHANGES MADE

21. (Amended) A device containing one or more polypeptides selected from the group consisting of the polypeptides shown in SEQ ID NO:1, SEQ ID NO:2, SEQ ID NO:3, SEQ ID NO:4, SEQ ID NO:5, SEQ ID NO:6, SEQ ID NO:7, [and variants thereof] and phenotypically silent amino acid substitution variants thereof.

23. (Amended) The device of claim 22, wherein the instructions for use indicate that the identification of an *Ehrlichia* infection is done using a method of detecting presence of antibodies to *Ehrlichia* comprising:

(a) contacting one or more polypeptides selected from the group consisting of the polypeptides shown in SEQ ID NO:1, SEQ ID NO:2, SEQ ID NO:3, SEQ ID NO:4, SEQ ID NO:5, SEQ ID NO:6, SEQ ID NO:7, [and variants thereof] and phenotypically silent amino acid substitution variants thereof, with a test sample suspected of comprising antibodies to *Ehrlichia*, under conditions that allow polypeptide/antibody complexes to form;

(b) detecting polypeptide/antibody complexes;

wherein the detection of polypeptide/antibody complexes is an indication that an *Ehrlichia* infection is present.

35. (New) A device containing one or more polypeptides selected from the group consisting of the polypeptides shown in SEQ ID NO:1, SEQ ID NO:2, SEQ ID NO:3, SEQ ID NO:4, SEQ ID NO:5, SEQ ID NO:6, SEQ ID NO:7, and conservative amino acid substitution variants thereof.

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36. (New) The device of claim 35, further comprising instructions for use of the one or more polypeptides for the identification of an *Ehrlichia* infection in a mammal.

37. (New) The device of claim 36, wherein the instructions for use indicate that identification of an *Ehrlichia* infection is done using a method of detecting presence of antibodies to *Ehrlichia* comprising:

(a) contacting one or more polypeptides selected from the group consisting of the polypeptides shown in SEQ ID NO:1, SEQ ID NO:2, SEQ ID NO:3, SEQ ID NO:4, SEQ ID NO:5, SEQ ID NO:6, SEQ ID NO:7 and conservative amino acid substitution variants thereof, with a test sample suspected of comprising antibodies to *Ehrlichia*, under conditions that allow polypeptide/antibody complexes to form;

(b) detecting polypeptide/antibody complexes;

wherein the detection of polypeptide/antibody complexes is an indication that an *Ehrlichia* infection is present.

38. (New) The device of claim 35, wherein the *Ehrlichia* infection is caused by *Ehrlichia canis* or *Ehrlichia chaffeensis*.

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